REMARKS/ARGUMENTS

Claims 67-94 are pending in this application. Claims 1-66 were previously canceled. The Office Action of July 29, 2008 has been received and considered. In the Office Action, claims 67-94 were rejected under 35 U.S.C. §112, first paragraph, 35 U.S.C. §112, second paragraph and 35 U.S.C. §103(a). Claims 67, 68, 71, 75, 80, 81, 83, 87, 91, and 92 have been amended. No new matter has been added by way of these claim amendments. Applicant asks that the claim amendments be entered and all claims be examined and allowed.

Request for Withdrawal of Finality

Applicants respectfully request that the Examiner withdraw the finality of the Office Action dated July 29, 2008.

In the Final Office Action, the Examiner cites two new objections to the claims. Claims 67-94 are rejected under 35 U.S.C. §112 first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner also rejects claims 67-94 under 35 U.S.C. §112 first paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The withdrawal of finality should be withdrawn because the rejections under 112 first and second paragraphs are new rejections. The Examiner states that the Applicant's amendment necessitated the new grounds of rejection; however, the Applicant's preliminary amendment canceled all previous pending claims (1-66) and added new claims (67-94) which contained new

limitations which had not been previously examined. A second or any subsequent action on the merits in any application should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed. See **MPEP § 904** *et seq.*

Accordingly, the present Office Action does not provide the Applicant with a fair opportunity to address these new rejections. Thus, the Applicant respectfully requests that the Examiner withdraw the finality of the Office Action.

Rejection of Claim 67-76, 79, and 81-94 under 35 U.S.C. 112, first paragraph

Claims 67-76, 79, and 81-94 have been rejected under 35 U.S.C. §112, first paragraph, as failing to provide an adequate written description of the invention and failing to adequately teach how to make and/or use the invention. Specifically, the Final Office Action asserts that claims 67-76, 79, and 81-94 that the ability to prolong a pregnancy at risk for preterm delivery is not known or common to the list of progestational agents disclosed by the Applicants. The premise of the Examiner's argument appears to be that the Applicants must demonstrate a working example of each and every progesterone-related agent within the limitation of the claims, and that the claimed invention is enabled only if no experimentation is required to use the claimed method. This requirement is not supported by the applicable case law.

The statutory basis of the enablement requirement under 35 U.S.C. § 112, first paragraph requires that the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the court stated:

"[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts." In the Final Office Action, the Examiner argues that the specification merely suggests the use of agents that retain the activity of progesterone to inhibit or delay delivery but provides no guidance for which agents retain such activity. Once again, the Examiner seems to be requiring that the Applicants describe each and every species in order to claim the genus.

For each claim drawn to a genus, the written description requirement may be satisfied through a sufficient description of a representative number of species identifying characteristics sufficient to show the applicant was in possession of the claimed genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Thus, there are two related elements of the written description requirement: 1) sufficient description; and 2) a representative number of species. Sufficient description can be shown by disclosure of relevant, identifying characteristics, (*i.e.*, structure or other physical and/or chemical properties). *Id.*; *see also* 66 Fed. Reg. 1099, 1106 (2000).

In the case of the first element, the Applicants have clearly provided sufficient description by disclosing the relevant identifying characteristics of the agent in question. "Progestational Agent" is specifically defined in paragraph [0056] of the specification as "any agent that favors, or is conducive to, gestation." Relevant identifying physical and chemical properties of progestational agents are further defined in the same paragraph of the specification as "... a group of hormones normally secreted by the corpus luteum and placenta, and in small amounts by the adrenal cortex..." as well as "... a member of a group of steroid compounds that are progesterones or progesterone derivatives

that retain progesterone activity that inhibits or delays delivery." The second element of the written description requirement, (i.e., a representative number of species), is also satisfied by the Applicants' specification. In paragraph [0056], there is a list of more than 45 exemplary progestational agents such as: dydrogesterone; ethynodiol diacetate; hydroxyprogesterone caproate; medroxyprogesterone acetate; norethindrone; norethindrone acetate; norethynodrel; norgestrel; megesterol acetate; gestodene; desogestrel; cingestol; lynestrenol; quingestanol acetate; levonorgestrel; 3-ketodesogestrel; norgestimate; osaterone; cyproterone acetate; trimegestone; dienogest; drospirenone; nomegestrol; (17-deacetyl)norgestimnate; 19-norprogesterone; melengestrol; ethisterone; medroxyprogesterone acetate; 17-.alpha.-hydroxyprogesterone; dimethisterone; ethinylestrenol; demegestone; promegestone; chlormadinone; pregn-4-ene-3,20-dione (progesterone); 19-nor-pregn-4-ene-3,20-dione; 17-hydroxy-19-nor-17.alpha- .-pregn-5(10)-ene-20-yn-3-one; dl-11.alpha.-ethyl-17-ethinyl-17-.alpha.-hy- droxygon-4-ene-3-one; 17-ethynyl-17-hydroxy-5 (10)-estren-3-one; 17.alpha.-ethynyl-19-norestosterone; 6-chloro-17-hydroxypregna-4,6-diene-- 3,20-dione; 17.alpha.-hydroxy-6.alpha.-methyl-17(-1-propynl-)androst-4-ene-3-one; 9.alpha.,10.alpha.-pregna-4,6-diene-3,20-dione; 17-hydroxy-17.alpha.-pregn-4-en-20-yne-3-one; 19-nor-17.alpha.-preg-4-en-20-yen-3,17-diol; 17-hydroxy-pregn-4-ene-3,20-dione; and 1-7-hydroxy-6.alpha.-methylpregn-4-ene-3,20-dione.

Thus, by providing both the relevant identifying physical and chemical properties of progestational agents as well as a number of representative species, the Applicants have satisfied written description test detailed in *Regents of the University of California v. Eli Lilly & Co.* Because of the description of these physical and chemical properties of the disclosed genus, the Applicants respectfully asserts that a sufficient description of the current invention has been shown and respectfully requests that the rejection under 35 U.S.C. §112, first paragraph is withdrawn.

Rejection of Claims 67-94 under 35 U.S.C. 112, first paragraph

Claims 67-94 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.. Specifically, the Final Office Action asserts that "...the Applicant does not define, and one would not readily know absent further guidance from applicant, what patients are encompassed by the current criteria of 'asymptomatic'." The Examiner goes on to further argue that even though any pregnant patient is contemplated by the invention "...such possibility of use does not provide explicit or implicit indication to one of skill in the art that only 'asymptomatic' patients were originally contemplated as part of applicant's invention..." The Applicants respectfully disagree.

In the background section of the specification (paragraph [0003]), the Applicants state that "...due to the subtlety of symptoms associated with preterm delivery, many subjects are not diagnosed as having an increased risk of preterm delivery until later in their pregnancies." (emphasis added) It is clear that the Applicants contemplated that the lack of symptoms (i.e., being asymptomatic) is a significant problem associated with preterm delivery. In paragraph [0085] of the specification, the Applicants specifically point what some of those symptoms may be by teaching that "...there are a large number of factors known to be associated with the risk of preterm delivery. Those factors include, but are not limited to, multiple fetus gestations; incomplete cervix; uterine anomalies; polyhydramnios; nulliparity; previous preterm rupture of membranes or preterm labor; preeclampsia; first trimester vaginal bleeding; little or no antenatal care; and symptoms such as abdominal pain, low backache, passage of cervical mucus and contractions." (emphasis added).

Thus, it is clear that the Applicants contemplated the issue of women who are asymptomatic of preterm delivery but who are still at risk of giving birth to a premature infant.

The Applicants respectfully asserts that the term "asymptomatic" is not new matter and respectfully requests that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

Rejection of Claims 67-94 under 35 U.S.C. 112, second paragraph

Claims 67-94 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicants have amended claims 67, 68, 71, 75, 80, 81, 83, 85, 86, 87, 91 and 92 to correct antecedent basis. Withdrawal of the rejections under 35 U.S.C. §112, second paragraph is respectfully requested.

The Rejections of the Claims under 35 U.S.C. § 103 Should Be Withdrawn

Claims 67 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Leavitt et al. (WO 94/17405) in view of Johnson et al. (NEJM 293: 675, 1975), Meis et al. (Am. J. Obstet. Gynecol. 187: S54, 2002), or Keirse (Br. J. Obstet. Gynaecol. 97: 149, 1990) and in further view of Weiner et al. or Anderson et al. This rejection is respectfully traversed.

In the Final Office Action, the Examiner argues that "...it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have tested a pregnant patient determined to have biochemical markers indicative of impending preterm delivery for the status of the fetal membranes and to treat those patients with intact fetal membranes indicated as at risk of having impending delivery with a pregnancy-prolonging agent because of the direct suggestion in Leavitt et al. to do so" The Applicants respectfully disagree with the Examiner that

Leavitt et al. in view of Johnson et al., Meis et al., or Keirse and in further view of Weiner et al. or Anderson et al. teach or suggest either alone or in combination, a method of screening and treating a subject who is asymptomatic for preterm or imminent delivery by administering a progestational agent as described in independent claim 67.

To properly establish a *prima facie* case of obviousness of a claim under 35 U.S.C. §103(a), all the claim limitations must be taught or suggested by the prior art, and all words in a claim must be considered in judging the patentability of that claim against the prior art. MPEP §2143.03. In the present case, currently amended independent Claim 67 (from which dependent claims 68-76 and 79-94 depend)

requires the express limitation of "...obtaining a sample from a subject who is asymptomatic for preterm or imminent delivery..." Nowhere in Leavitt et al., Johnson et al., Meis et al., Keirse, Weiner et al. or Anderson et al., either alone or in combination, is there any teaching or suggestion of testing and treating an asymptomatic patient. Without this teaching, the references cited by the Examiner are insufficient to show obviousness. Therefore, Applicant respectfully submits that claims 67-76 and 79-94 are patentable over the cited references.

Claims 77 and 78 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Leavitt et al. (WO 94/17405) in view of Johnson et al. (NEJM 293: 675, 1975), Meis et al. (Am. J. Obstet. Gynecol. 187: S54, 2002), or Keirse (Br. J. Obstet. Gynaecol. 97: 149, 1990) and in further view of Weiner et al. or Anderson et al. and in further view of Allen et al. (Exp. Biol. Med. 226:498, 2001) or Olsen et al. (Lancet 339: 1003, 1992). For all the reasons stated above, Leavitt et al., Johnson et al., Meis et al., Keirse, Weiner et al. or Anderson et al., Allen, or Olsen do not teach or suggest, either alone or in combination, a method of screening and treating a subject who is asymptomatic for

preterm or imminent delivery by administering a progestational agent as described in currently amended independent claim 67 (from which claims 77 and 78 depend). Without this teaching, the references cited by the Examiner are insufficient to show obviousness. Therefore, Applicant respectfully submits that claims 77 and 78 are patentable over the cited references.

CONCLUSION

Applicant respectfully requests entry of this Amendment After Final in order to place the application in condition for allowance. If there are any questions concerning this amendment and response, please contact the undersigned at the number below.

A one-month extension of time is respectfully requested. It is believed that no additional fees are required for this submission. If any additional fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 502855, accordingly. If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicants, the Examiner is invited to contact Applicant's' attorney at the number noted below.

Respectfully submitted,

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